April 26, 2023

Olympus Medical Systems Corporation
% Darlene Hull
Regulatory Program Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, MA 01581

Re: K222584
Trade/Device Name: Evis X1 Video System Center Olympus CV-1500, Colonovideoscope Olympus CF-HQ1100DL/I, Gastrointestinal Videoscope Olympus GIF-1100
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FET, NWB, NTN, FDF, FDS
Dated: March 23, 2023
Received: March 23, 2023

Dear Darlene Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222584

Device Name
CV-1500, CF-HQ1100DL, CF-HQ1100DI, GIF-1100

Indications for Use *(Describe)*

EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

The EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 is intended to be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product is designed to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis. The CV-1500 Video System Center is compatible with scopes within the EVIS 190 and 1100 families.

COLONOSCOPE OLYMPUS CF-HQ1100DL & CF-HQ1100DI

The COLONOVIDEOSCOPE OLYMPUS CF-HQ1100DL/I is intended to be used with an Olympus video system center, endoscope position detecting unit, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The COLONOVIDEOSCOPE CF-HQ1100DL &CF-HQ1100DI (product codes may be combined into a shorter code: CF-HQ1100DL/I) is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1100

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1100 is intended to be used with an Olympus video system center, Light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The GASTROINTESTINAL VIDEOSCOPE GIF-1100 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: August 25, 2022

510(k) Summary

1. GENERAL INFORMATION

510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507

Contact Person: Darlene R. Hull
Olympus Corporation of the Americas
800 West Park Drive
Westborough, MA 01581
Phone: 385-7996752
Email: darlene.hull@olympus.com

Manufacturing site: *Manufacturer for CF-HQ1100DL,CF-HQ1100DI and GIF-1100*
Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

Manufacturer for CV-1500
Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan

2. DEVICE IDENTIFICATION

2-1. CV-1500

Device Name: EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

[New components]

- FOOT HOLDER MAJ-2431
- Power code 3.0m MAJ-2270
- Water container MAJ-901
- Portable memory 2 MAJ-2427
- 12G SDI cable MAJ-2428
- White cap set MAJ-941
- Pump remote cable MAJ-920

[New accessories]

- WATER CONTAINER MAJ-902
- 12G-SDI cable 1.5M MAJ-2426
- 12G-SDI cable 2.9M MAJ-2428
- 12G-SDI cable 8.5M MAJ-2429
- 3G-SDI cable 1.5M MAJ-2430
- Y/C Cable MH-985
- Footswitch Conversion Cable MAJ-2437

Model Name:	OLYMPUS CV-1500
Common Name:	ENDOSCOPIC VIDEO IMAGING SYSTEM
Classification Number:	876.1500
Classification Name:	Endoscope and accessories
Regulatory Class:	II
Product Code (Product Code Name):	FET (Endoscopic Video Imaging System/Component, Gastroenterology-Urology), NWB (Endoscope, Accessories, Narrow Band Spectrum), NTN (Led Light Source)
Device Panel:	Gastroenterology/Urology

2-2. CF-HQ1100DL and CF-HQ1100DI

Device Name:	COLONOSCOPE OLYMPUS CF-HQ1100DL & CF-HQ1100DI
Model Name:	OLYMPUS CF-HQ1100DL & CF-HQ1100DI
Common Name:	COLONOSCOPE
Classification Number:	876.1500
Classification Name:	Endoscope and accessories
Regulatory Class:	II
Product Code (Product Code Name):	FDF (Colonoscope And Accessories, Flexible/Rigid), NWB (Endoscope, Accessories, Narrow Band Spectrum)

Device Panel: Gastroenterology/Urology

2-3. GIF-1100

Device Name: GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1100
Model Name: OLYMPUS GIF-1100
Common Name: GASTROINTESTINAL VIDEOSCOPE
Classification Number: 876.1500
Classification Name: Endoscope and accessories
Regulatory Class: II
Product Code (Product Code Name): FDS (Gastroscope and accessories, flexible/rigid), NWB (Endoscope, Accessories, Narrow Band Spectrum)
Device Panel: Gastroenterology/Urology

3. PREDICATE DEVICE

Predicate device for CV-1500

Device name	510(k) Submitter	510(k) No.
VIDEO SYSTEM CENTER OLYMPUS CV-190	OLYMPUS MEDICAL SYSTEMS CORP.	K131780
XENON LIGHT SOURCE OLYMPUS CLV-190	OLYMPUS MEDICAL SYSTEMS CORP.	K131780

Predicate device for CF-HQ1100DL & CF-HQ1100DI

Device name	510(k) Submitter	510(k) No.
COLONOVIDEOSCOPE CF-HQ190L/I	OLYMPUS MEDICAL SYSTEMS CORP.	K131780

Predicate device for GIF-1100

Device name	510(k) Submitter	510(k) No.
GASTROINTESTINAL VIDEOSCOPE GIF-H190	OLYMPUS MEDICAL SYSTEMS CORP.	K131780

4. DEVICE DESCRIPTION

General Device Description

This video system center is intended to be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product is designed to process electronic signals transmitted from Olympus video endoscopes, output images

to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis.

RDI (Red Dichromatic Imaging) observation:

RDI is optical-digital observation using red dichromatic narrow band light and green illumination light to enhance visibility of bleeding points in the endoscopic image due to the difference in light absorption.

TXI (TeXture and color enhancement Imaging):

TXI emphasizes tonal changes, patterns, and image outlines. It also corrects the brightness of dark areas.

BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast):

BAI-MAC maintains the brightness of the bright part of the endoscopic image and corrects the brightness of the dark part of the endoscopic image.

EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

This video system center is indicated to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, and be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product also functions as a pump to supply air through the endoscope, a light source to the endoscope, and a controller/monitor of ancillary equipment.

COLONOSCOPE OLYMPUS CF-HQ1100DL &CF-HQ1100DIGASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1100

The endoscope receives the illumination light from light guide connector connected to the video system center (CV-1500: part of this submission). The illumination light is transferred to the distal end through the optical fiber bundle inside of the endoscope and illuminates the inside of the patient body through the illumination lens at the distal end.

The endoscope receives the reflected light from the inner lumen of a patient by objective lens at the distal end. The built-in CCD at the distal end converts the light to the electrical signal, and the signal is sent to the video system center via the electrical cable and the video connector of the endoscope. The endoscope transfers

the image signal and displays the observation image on the screen.
The endoscope consists of three parts: the control section, the insertion section, and the connector section. The basic principle including user interface and operation for the procedure of the endoscope is identical to that of the predicate device.

5. INDICATIONS FOR USE

EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

The EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 is intended to be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product is designed to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis. The CV-1500 Video System Center is compatible with scopes within the EVIS 190 and 1100 families.

COLONOSCOPE OLYMPUS CF-HQ1100DL & CF-HQ1100DI

The COLONOVIDEOSCOPE OLYMPUS CF-HQ1100DL/I is intended to be used with an Olympus video system center, endoscope position detecting unit, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The COLONOVIDEOSCOPE CF-HQ1100DL &CF-HQ1100DI (product codes may be combined into a shorter code: CF-HQ1100DL/I) is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1100

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1100 is intended to be used with an Olympus video system center, Light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The GASTROINTESTINAL VIDEOSCOPE GIF-1100 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

CV-1500

	Subject Device CV-1500	Primary Predicate Device CV-190 (K131780)	Secondary Predicate Device CLV-190 (K131780)
510(k) number	This submission	K131780	K131780
Regulation number	876.1500	876.1500	876.1500
Regulatory class	Class II	Class II	Class II
Product code	FET (endoscopic video imaging system/component, gastroenterology-urology) NWB(endoscope, accessories, narrow band spectrum) NTN (led light source)	FDF (colonoscope and accessories, flexible/rigid) FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)	FDF (colonoscope and accessories, flexible/rigid) FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)
Classification panel	Gastroenterology and urology	Gastroenterology and urology	Gastroenterology and urology
Common name	EVIS X1 VIDEO SYSTEM CENTER	EVIS EXERA III VIDEO SYSTEM CENTER	EVIS EXERA III XENON LIGHT SOURCE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Indications for use	This video system center is intended to be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product is designed to process electronic signals transmitted from Olympus video endoscopes,	This video system center is intended to be used with OLYMPUS camera heads, endoscopes, light sources, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video	This light source is intended to be used With Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

	Subject Device CV-1500	Primary Predicate Device CV-190 (K131780)	Secondary Predicate Device CLV-190 (K131780)
	output images to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis. Compatible scope family: EVIS 190 series, 1100 series.	observation.	
Rated voltage	100 -120V AC ±10 %	100 - 120 V AC ± 10%	100 - 120 V AC ± 10%
Rated frequency	50/60 Hz ± 1 Hz	50/60 Hz ± 1 Hz	50/60 Hz ± 1 Hz
Over-current protection	Fuse type (Built-in type)	Fuse type (Built-in type)	Fuse type (Built-in type)
Rated input	600 VA	150 VA	600 VA

	Subject Device CV-1500	Primary Predicate Device CV-190 (K131780)	Secondary Predicate Device CLV-190 (K131780)
Dimensions (W×H×D)	370×198×488 mm	370×85×455 mm	370×150×476 mm
Dimensions (maximum) (W×H×D)	398×218×580 mm	382×91×489 mm	382×162×551 mm
Weight	19.4 kg	10.7 kg	19 kg
Bulb type	LED		Xenon short-arc lamp (ozone-free)300W
Providing maximum light intensity	Less than 3.93 W		3.21 W
Observation mode	WLI, NBI, RDI		WLI, NBI
Emergency Lamp	Not provided		Halogen Lamp 12V35W
Brightness adjustment	• Automatic (current control, 17 steps)		• Automatic (current control, 17 steps) • Manual (current control, 17 steps)
Touch panel	Provided (Brightness 10 steps)	Not provided	Not provided

	Subject Device CV-1500	Primary Predicate Device CV-190 (K131780)	Secondary Predicate Device CLV-190 (K131780)
Communication terminals	• Output socket • 1000BASE-T • Foot switch • Keyboard • Adaptor • Recorder • DF • Printer • CV-LINK • LINK OUT • UPD/PSCU	• Video connector socket • 100BASE-TX • Foot switch • Key board • Option 1 • Option 2 • Adapter • Light source • Light source 2 • Remote 1 • Remote 2 • Monitor remote 1 • Monitor remote 2 • EUS • CV-LINK	• Output socket • CV 1 • CV 2 • LINK – OUT • UPD
Analog signal output	VBS composite	RGB component VBS composite and Y/C; simultaneous outputs possible.	
Digital signal output	SDI:2	SDI:2, DVI:1	
Observation mode	WLI, NBI, RDI	WLI, NBI	WLI, NBI
User settings	The function settings for up to 20 users can be stored.	The function settings for up to 20 users can be stored.	

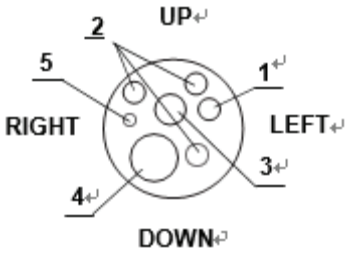
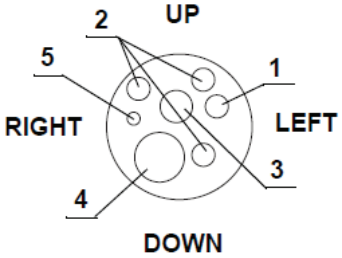
	Subject Device CV-1500	Primary Predicate Device CV-190 (K131780)	Secondary Predicate Device CLV-190 (K131780)
White Balance adjustment	**190Series** Automatically adjusted using the white balance switch at the time of connection with the scope with Scope ID. **1100Series** Automatically adjusted without pressing white balance switch	Automatically adjusted using the white balance switch at the time of connection with the scope with Scope ID.	
Standard color chart output	Color bar image	Color bar image or the 50% white screen can be displayed	
Color tone adjustment	• Red adjustment ±8 steps • Blue adjustment ±8 steps • Chroma adjustment ±8 steps	• Red adjustment ±8 steps • Blue adjustment ±8 steps • Chroma adjustment ±8 steps	
Contrast	Normal / High / Low	Normal / High / Low	
Iris	AUTO/PEAK/AVE	AUTO/PEAK/AVE	
Image enhancement	Structure enhancement Type A: (8 steps). Type B: (8 steps). *User can preset three image enhancement settings	Structure enhancement Type A: (8 steps). Type B: (8 steps). Edge enhancement (8 steps). *User can preset three image enhancement settings	
TXI modes	Mode 1/Mode 2/Mode 3	Not provided	

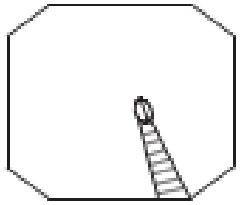
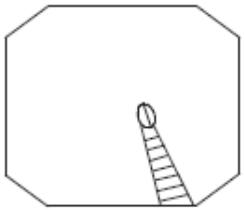
	Subject Device CV-1500	Primary Predicate Device CV-190 (K131780)	Secondary Predicate Device CLV-190 (K131780)
Image size selection	The size of the endoscopic image can be selected from 2 modes. (Except SDTV)	The size of the endoscopic image can be selected from 2 modes. (Except SDTV)	
Electric zoom	Switch between mode 1, mode 2, and mode 3.	Switch between mode 1, mode 2, and mode 3.	
PIP/POP	Provided	Provided	
Aspect ratio	Switch between 16:9 and 4:3. (Except SDTV)	Switch between 16:9 and 4:3. (Except SDTV)	
Freeze	Still the endoscopic image.	Still the endoscopic image.	
Pre-freeze	Available	Available	
Custom switch	Assign specific functions to the following buttons. • Remote switches (Up to 5) • Foot switches (Up to 2) • Keyboard custom key (Up to 4) • Touch panel custom button of basic functions screen (Up to 3) • Touch panel custom button of custom functions screen (Up to 10)	Assign specific functions to the following buttons. • Remote switches (Up to 5) • Foot switches (Up to 2) • Keyboard custom key (Up to 4)	
Pump	Diaphragm type pump		Diaphragm type pump
Pressure switching	4-level available (OFF, low, medium, high)		4-level available (OFF, low, medium, high)

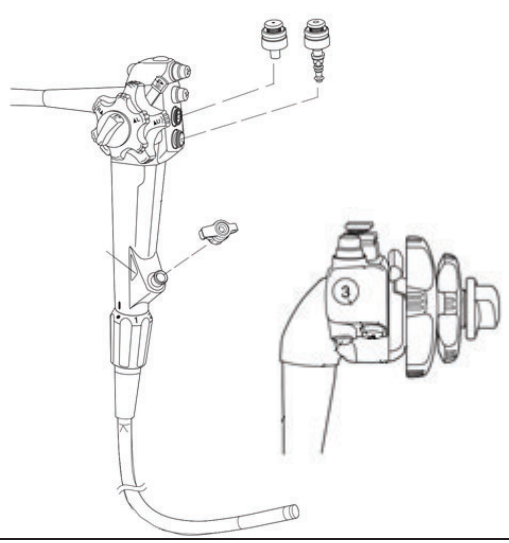
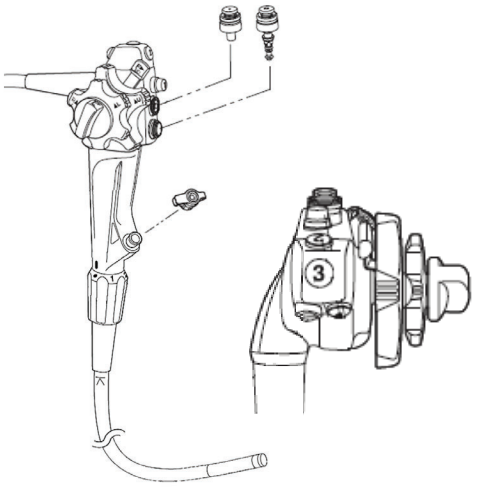
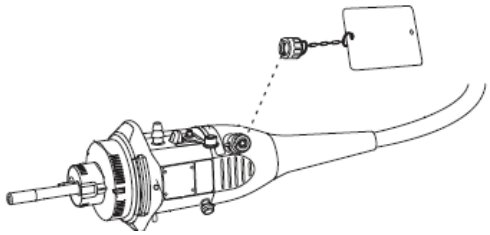
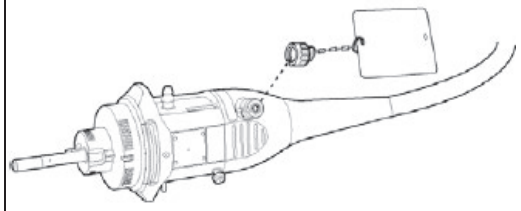
	Subject Device CV-1500	Primary Predicate Device CV-190 (K131780)	Secondary Predicate Device CLV-190 (K131780)
Water Feeding Method	Can be supplied from the distal end of the endoscope in combination with the OLYMPUS water container.		Can be supplied from the distal end of the endoscope in combination with the OLYMPUS water container.
Compatible water container	MAJ-901, MAJ-902		MAJ-901, MAJ-902
Record to portable memory	Provided	Provided	Not provided
Cooling method of inside	Fan (Variable rotation)	Fan (Forced-air cooling)	Fan (Variable rotation)
Type of protection against electric shock	Class I	Class I	Class I
Degree of protection against electric shock of applied part	Type BF applied part (Depends on applied part)	Type BF or CF applied part (Depends on applied part)	TYPE BF or CF applied part (Depend on applied part)
Degree or protection against explosion	The video system center should be kept away from flammable gases.	The video system center should be kept away from flammable gases.	The light source should be kept away from flammable gases.

CF-HQ1100DL & CF-HQ1100DI

	Subject Device **CF-HQ1100DL** **CF-HQ1100DI**	**Predicate Device** **CF-HQ190L/I**
510(k) number	This submission	K131780
Regulation number	876.1500	876.1500
Regulatory class	Class II	Class II
Product code	FDF (colonoscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)	FDF (colonoscope and accessories, flexible/rigid) FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)
Classification panel	Gastroenterology and urology	Gastroenterology and urology
Common name	COLONOVIDEOSCOPE	COLONOVIDEOSCOPE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Indications for use	This instrument is intended to be used with an Olympus video system center, endoscope position detecting unit, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The COLONOVIDEOSCOPE CF-HQ1100DL/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).	This instrument is intended to be used with an Olympus video system center, endoscope position detecting unit, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The EVIS EXERA III COLONOVIDEOSCOPE CF-HQ190L/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).
Type	- CCD - CYM color filter - Sequential read image signal	- CCD - CYM color filter - Sequential read image signal

	Subject Device CF-HQ1100DL CF-HQ1100DI	Predicate Device CF-HQ190L/I
Direction of View	0°	0°
Field of View	Normal focus mode: 170° Near focus mode: 160°	Normal focus mode: 170° Near focus mode: 160°
Depth of Field	Normal focus mode: 5 - 100 mm Near focus mode: 2 - 6 mm	Normal focus mode: 5 - 100 mm Near focus mode: 2 - 6 mm
Distal end outer diameter	13.2 mm	13.2mm
Maximum distal end outer diameter	14.9 mm	14.9 mm
Distal end enlarged	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel
Insertion tube outer diameter	12.8 mm	12.8mm

	Subject Device CF-HQ1100DL CF-HQ1100DI	Predicate Device CF-HQ190L/I
Insertion section working length	L: 1680 mm I: 1330 mm	L: 1680 mm I: 1330 mm
Channel inner diameter	3.7 mm	3.7 mm
Minimum channel inner diameter	3.7 mm	3.7 mm
Minimum visible distance	4 mm (Normal focus mode)	4 mm (Normal focus mode)
Direction from which EndoTherapy accessories enter and exit the endoscopic image		

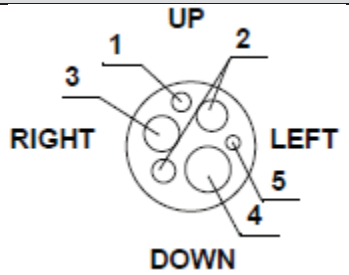
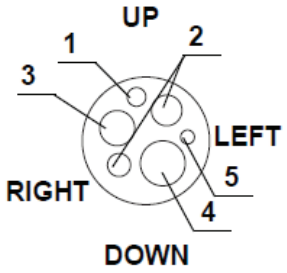
	Subject Device CF-HQ1100DL CF-HQ1100DI	Predicate Device CF-HQ190L/I
Configuration		
Configuration		
Airflow rate	25 cm^3/s (CV-1500)	25 cm^3/s (CLV-190, CV-1500)

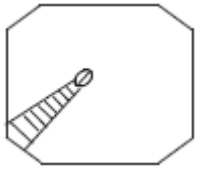
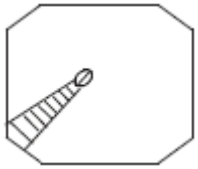
	Subject Device CF-HQ1100DL CF-HQ1100DI	Predicate Device CF-HQ190L/I
Angulation range	UP 180° DOWN 180° RIGHT 160° LEFT 160°	UP 180° DOWN 180° RIGHT 160° LEFT 160°
Total length	L: 2005 mm I: 1655mm	L: 2005 mm I: 1655mm
Pre-freeze function	Available	Available
Electronic zoom function	Available	Available
Electronic shutter function	Available	Available
Records of endoscope's information	Available	Available
NBI observation	Available	Available
RDI observation	Available (when using CV-1500)	Available (when using CV-1500)
High frequency cauterization treatment	Available	Available
Endoscope position detecting function	Available	Available

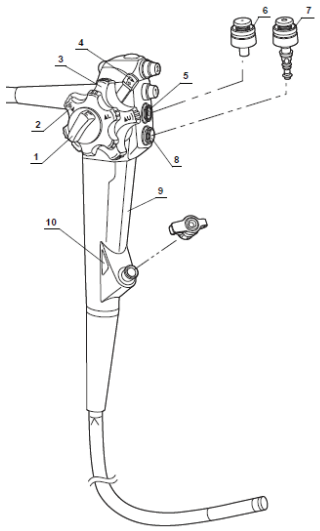
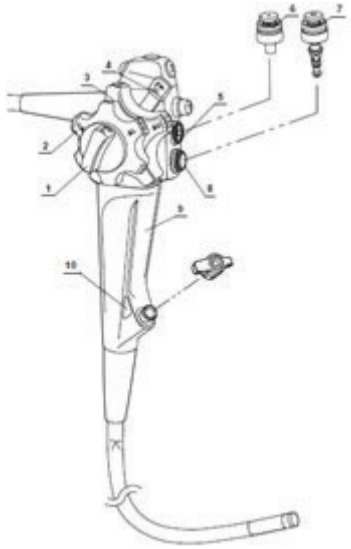
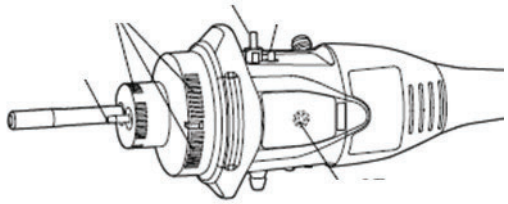
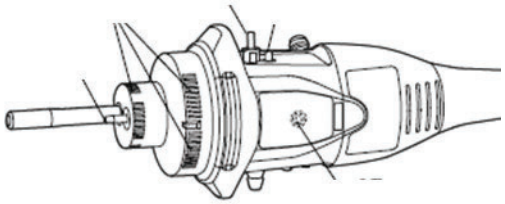
	Subject Device CF-HQ1100DL CF-HQ1100DI	Predicate Device CF-HQ190L/I
Passive bending function	Available	Available
Flexibility adjustment function	Available	Available
Focus switching function	Available	Available
Auxiliary water feeding function	Available	Available

GIF-1100

	Subject Device GIF-1100	**Predicate Device GIF-H190**
510(k) number	This submission	K131780
Regulation number	876.1500	876.1500
Regulatory class	Class II	Class II
Product code	FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)	FDF (colonoscope and accessories, flexible/rigid) FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)
Classification panel	Gastroenterology and urology	Gastroenterology and urology
Common name	GASTROINTESTINAL VIDEOSCOPE	GASTROINTESTINAL VIDEOSCOPE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Indications for use	This instrument is intended to be used with an Olympus video system center, Light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The GASTROINTESTINAL VIDEOSCOPE GIF-1100 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).	This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-H190 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).
Direction of View	0°	0°
Field of View	140°	140°
Depth of Field	2 - 100 mm	2 - 100 mm

	Subject Device GIF-1100	Predicate Device GIF-H190
Distal end enlarged	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel
Distal end outer diameter	8.9 mm	9.2 mm
Maximum distal end outer diameter	10.7mm	11.2 mm
Insertion tube outer diameter	8.9 mm	9.2mm
Insertion section working length	1030 mm	1030 mm
Channel inner diameter	2.8 mm	2.8 mm

	Subject Device GIF-1100	Predicate Device GIF-H190
Minimum visible distance	3 mm	3 mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image		

	Subject Device GIF-1100	Predicate Device GIF-H190
Configuration		
Configuration		
Airflow rate	25 cm^3/s (CV-1500)	25 cm^3/s(CLV-190, CV-1500)

	Subject Device GIF-1100	Predicate Device GIF-H190
Angulation range	UP 210° DOWN 90° RIGHT 100° LEFT 100°	UP: 210° DOWN: 90° RIGHT:100° LEFT:100°
Total length	1350 mm	1350 mm
Pre-freeze function	Available	Available
Electronic zoom function	Available	Available
Electronic shutter function	Available	Available
Records of endoscope's information	Available	Available
NBI observation	Available	Available
RDI observation	Available (when using CV-1500)	Available (when using CV-1500)
Structure enhancement type B	Available	Available
Image size large 1	Available	Available
High frequency cauterization treatment	Available	Available
Endoscope position detecting function	Not available	Not available
Passive bending function	Not Available	Not Available

	Subject Device GIF-1100	Predicate Device GIF-H190
Flexibility adjustment function	Not Available	Not Available
Focus switching function	Not Available	Not Available
Auxiliary water feeding function	Available	Available

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) **Reprocessing validation**
   Reprocessing instruction and reprocessing method validation testing were conducted for CF-HQ1100DL/I and GIF-1100, and documentations were provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

2) **Biocompatibility**
   Biocompatibility evaluation were conducted for CF-HQ1100DL/I, GIF-1100, CV-1500, and MAJ-901/902 in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

   - Cytotoxicity Study Using the Elution Method
   - Intracutaneous Irritation Study
   - Guinea Pig Maximization Sensitization Test

3) **Software verification and validation**
   Software verification and validation testing were conducted for CV-1500, CF-HQ1100DL, CF-HQ1100DI, and GIF-1100, and documentations were provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

4) **Electrical safety and electromagnetic compatibility (EMC)**
   Electrical safety and EMC testing were conducted for CV-1500, CF-HQ1100DL, CF-HQ1100DI, and GIF-1100 in accordance with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC. Laser safety test was conducted for CV-1500 in accordance with the IEC 60825-1:2007 standards for laser product.

5) **Performance testing - Bench**
   Bench testing as listed below were conducted for CV-1500, CF-HQ1100DL, CF-HQ1100DI, and GIF-1100 to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety
- Durability
- Photobiological Safety
- Color Performance
- Direction of View
- Field of View
- Resolution
- Depth of Field
- Noise and Dynamic Range
- Image Intensity Uniformity
- Video Latency
- RDI
- TXI and BAI-MAC
- Automatic Brightness Adjustment
- Pre-Freeze
- Geometric Distortion

6) Performance testing - Animal

Animal study was performed for CV-1500 to confirm the White Light Imaging (WLI) and Narrow Band Imaging (NBI) performance, and the effectiveness of Red Dichromatic Imaging (RDI) and TeXture and color enhancement Imaging (TXI) .

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk management

Risk management was performed for CV-1500, CF-HQ1100DL, CF-HQ1100DI,¥ and GIF-1100 in accordance with ISO 14971:2007. The design verification tests, and their acceptance criteria were identified and performed as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the EVIS X1 system raises no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.